What Implant Factors Affect Bone Ingrowth in Retrieved Porous Tantalum Hip Implants?

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Introduction: Over the past decade, several manufacturers have produced new highly porous metals aimed at increasing the bone-implant interface strength through bone ingrowth [1-2]. Initial large-scale clinical studies of porous tantalum hip implants have been generally promising with well-fixed implants and relatively few reported cases of loosening [3-4]. However, retrieval studies of porous tantalum tibial trays have been limited to small numbers of retrieved devices [3-4]. The goals of this study were to investigate bone ingrowth of retrieved porous tantalum acetabular shells and femoral stems. We asked: (1) Will the amount of bone vary based on location? (2) Will implant type (shell vs stem) affect the amount or location of bone ingrowth? (3) Do patient/clinical factors affect bone ingrowth?

Methods: Between 2003 and 2013, 126 porous tantalum acetabular shells and 7 femoral stems were retrieved during revision surgeries under an IRB approved multicenter program. Acetabular shells that were grossly loose, cemented or complex revisions were excluded. Shells with visible bone on the surface were chosen. 20 acetabular shells (10 primary) and all femoral stems were dehydrated, embedded, sectioned, polished and bSEM imaged (Figure-1). Main shell revision reasons were infection (n=10, 50%), femoral loosening (n=3, 15%) and instability (n=3, 15%). Analyzed implants were implanted for 2.3±1.7 years (shells) and 0.3±0.3 years (stems). Eight slices per shell and 5-7 slices per stem were analyzed. The bone ingrowth measurements consisted of Bone Area/Pore Area (BA/PA), BA/PA depth analysis, extent of ingrowth and maximum depth of ingrowth. The BA/PA represents the fraction of available pore space within the porous coating that was occupied by bone. The zones for BA/PA depth analysis were defined as: zone 1 (0-500µm), zone 2 (500-1000µm) and zone 3 (1000µm - full depth). The extent of bone ingrowth provides a topological indication of the distribution of bone ingrowth across the surface of the implant. The extent of ingrowth was calculated as the number of 1 mm sectors with
ingrowth divided by the total number of sectors expressed as a percentage. The maximum depth was defined as the deepest point where bone was present in the substrate and expressed as a percentage. Nonparametric statistical tests were used to investigate differences in BA/PA by location, design and depth (Related samples - Friedman’s Two-Way Analysis of Variance by Ranks, Non-related - Mann-Whitney). Post-hoc Dunn tests were completed for subsequent pairwise comparisons. Spearman’s rank correlation identified correlations between bone measurements and patient related variables (implantation time, age, height, weight, UCLA Activity Score). Statistical analyses were performed using PASW Statistics package.

**Results:** BA/PA in the superior region (4.1±2.4%) of the acetabular shells was significantly higher than in the inferior region (2.0±2.1%, p=0.047). Acetabular shells BA/PA in Zone-1 (10.8%, Figure 1) was significantly higher than Zone-2 (4.9%, p=0.013) and Zone-3 (1.6%, p<0.001). BA/PA was significantly higher in Zone-1 (10.8%) than Zone-3 (2.3%, p=0.043) for femoral stems. There were 9 shells and 2 stems (Figure 2) with full bone ingrowth into the porous tantalum substrate. When bone did not bridge the entire depth, a superficial layer of dense trabecular bone, integrated with the porous layer, was often observed. Localized regions of increased ingrowth were observed around screw holes of the acetabular shells. BA/PA was not significantly different between acetabular shells (3.6±3.3%) and femoral stems (5.8% ± 3.9%, p=0.068).Extent of ingrowth was similar between shells (42 ± 28%) and stems (47±26%, p=0.825). Acetabular shells (76±23%) and stems (82±23%, p=0.707) had a similar maximum ingrowth depth. There were no correlations between clinical/patient factors and bone measurements for both the acetabular shells and femoral stems.

**Discussion:** Our results demonstrated that bone ingrowth in porous tantalum components is concentrated in the superficial 500 um (Zone 1). This may provide the opportunity to reduce the thickness of the porous layer thus conserving more bone in future designs. Our results showed no difference in BA/PA between the shells and stems, most likely due to the low number of stems and their short implantation time. Bone ingrowth in the acetabular shells was preferentially located around screw holes and superior region, similar to previous studies of other cementless designs. Only 40% of analyzed acetabular shells had implantation times greater than 2 years. Further work focused on longer term retrievals will increase the understanding of the bone-implant interface.

**Significance:** Clinical studies of highly porous metals, such as porous tantalum, have shown well-fixed implants with a low incidence of loosening. To date, there has been limited analysis of retrieved porous tantalum hip implants. This study investigates factors which affect bone ingrowth into retrieved porous tantalum hip implants.